

# Using Your New *Esteem*®



Caution: Federal Law restricts this device to sale by or on the order of a physician.

# Patient Notes

Name of Your Physician: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Name of Your Hospital: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

## **Your Esteem® Sound Processor**

Model Number: \_\_\_\_\_

Serial Number: \_\_\_\_\_

Date of Implant: \_\_\_\_\_

## **Your Esteem® Sensor**

Model Number: \_\_\_\_\_

Serial Number: \_\_\_\_\_

Date of Implant: \_\_\_\_\_

## **Your Esteem® Driver**

Model Number: \_\_\_\_\_

Serial Number: \_\_\_\_\_

Date of Implant: \_\_\_\_\_

## **Special Instructions:**

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# Precautions

## Physical Activities and Sports

When your Health Care Professional says it is okay, you can return to most of the activities you enjoyed before receiving your *Esteem*®. Avoid contact sports and physical activities that could result in a hard blow to your head. Avoid diving deeper than 10 m (30 ft) of water, as this may result in damage to your *Esteem*®. If you have any questions concerning your activities, check with your Health Care Professional.

## Pushing or Twisting the Implanted Parts of Your *Esteem*®

Avoid pushing or twisting the implanted parts of your *Esteem*®, such as the Sensor and Driver leads. Either action can cause skin erosion or damage to various parts of the *Esteem*®. Skin erosion or *Esteem*® damage may require surgery to correct.

## Travel

*Esteem*® may set off security devices in airports. If it does, show your identification card to the security guard. Security systems and metal detectors could temporarily interrupt your hearing. To restore normal hearing, simply move away from the source of interference.

## Electrical Devices

Your *Esteem*® is designed to be resistant to interference produced by other electrical equipment such as household appliances. You may safely operate all common household appliances and office equipment. It is possible that while operating these appliances or equipment you may hear noise/interference, however the programming is unaffected. Moving away from the source will, in most cases, mitigate any potential interference.

## Magnetic Resonance Imaging (MRI)

You cannot undergo Magnetic Resonance Imaging (MRI) examination or be in close proximity to MRI devices after you have had *Esteem*® implanted. Fields produced by the MRI may damage your *Esteem*® or cause it to operate improperly.

## Clothing and Protective Equipment

Helmets and hats do not present a problem as long as they do not put a significant amount of pressure on the side of the head behind the ear where the Sound Processor is implanted. As customary in loud environments, the use of an earplug is recommended.

# Additional Precautions

If you are going to undergo a medical treatment or diagnostic procedure, you must notify your physician that you have an *Esteem*®.

The effects on the *Esteem*® of positron emission tomography (PET) scans, ultrasound, diathermy, radiation, external defibrillation, lithotripsy, radio frequency (RF) ablation, transcutaneous electrical nerve stimulation (TENS), and other electronic therapies have not been tested. If you require such treatment, you should let

**your physician know to consult with Envoy Medical for current safety information regarding these therapies. During all these types of therapies the *Esteem*® should always be turned off to avoid interference noises. X-Ray image quality directly around the implant could be compromised. Please avoid electroconvulsive therapy on or near the Sound Processor implant. During emergency use of a defibrillator, the *Esteem*® should be switched off to avoid interference noises. If emergency**

defibrillation is necessary, the *Esteem*® performance and integrity should not change. If you believe you have experienced any changes after this procedure, please contact your implanting surgeon or Envoy Medical Corporation.

- If your profession requires you to be in the vicinity of a high electrical current, consult your physician before engaging in such activities.
- People who smoke need to be aware that smoking can affect healing after any surgical procedure, including implantation of *Esteem*®.
- People with diabetes that is not well controlled with medication or diet need to take extra precaution with their surgeon to discuss post-operative healing issues.
- An *Esteem*® Implant has an approximate revision rate of 5%, requiring patients to have an additional surgical procedure to increase benefit.

### Colds and Allergies

Cold, sinus or upper respiratory congestion may result in temporarily reduced performance of the *Esteem*®. Please use your Personal Programmer to make appropriate adjustments during this time.

### AAA Battery Disposal

The Personal Programmer is powered by two AAA alkaline batteries. For instructions on how to replace the batteries see page 12.

### Immediately After Surgery

Immediately after the surgery, you will not be able to hear through the ear in which the *Esteem*® is implanted. This is not a cause for concern because the *Esteem*® is not yet turned on. Your doctor will determine when the *Esteem*® will be turned on.

# When to Call Your Doctor

## Call your doctor if:

- You get dizzy or existing dizziness gets worse
- You have drainage from your ear
- The discomfort from your surgery doesn't lessen with time
- You develop an elevated temperature or fever
- Your incision is hot to touch or very tender
- Your face gets weak or your eyelid will not close

If you have experienced any other unexplained symptoms, call your doctor.

# Your “Patient Identification” Card

**medical**  
**ENVOY**

**Esteem Hearing Implant ID-Card**

**Patient:**  
**Physician:**  
**Implant Clinic:**  
**Clinic Phone ☎:**  
**Initial Implant Date:**  
**Date:**  
**Date:**  
**Date:**

**Driver S/N:**  
**Sensor S/N:**  
**Sound Proc S/N:**

For Reference Only

Please inform your physician regarding your implanted hearing system, in case one of the following diagnostics/therapies is planned:

MRI, PET, RF-Ablation, TENS, Elektroconvulsive Therapy, Electrosurgery/cautery, Ultrasound, Diathermy, Radiation, Lithotripsy.

The implanted device may cause a signal during security checks (airport). See your patient manual.

If found please return this card to:

Envoy Medical Corporation, 5000 Township Parkway, Saint Paul, MN 55110, U.S.A.  
☎ +1 (651) 361-8000 USA ☎ +1 (866) 950-HEAR (4327) [www.envoymedical.com](http://www.envoymedical.com)

As soon as you receive your *Esteem*®, you will receive a temporary identification card. This will be replaced by a permanent identification card that will be sent to you.

## The Identification Card:

- Identifies you as a patient with an implanted hearing device
- Supplies basic information about your *Esteem*®
- Provides your doctor's name and telephone number

This identification card should be carried with you at all times.



## Using the *Esteem*®

Your physician will determine when to turn on your *Esteem*®. At that time, your *Esteem*® will be programmed to specifically meet your hearing needs.

### How to Adjust Your *Esteem*®

After your *Esteem*® is implanted and programmed, you can use your Personal

Programmer to activate the *Esteem*®, change the environment setting, adjust the volume, and query the current settings of your *Esteem*®. You can also put the system in standby mode, at any time. Using the standby mode prolongs battery life of the implanted *Esteem*®.

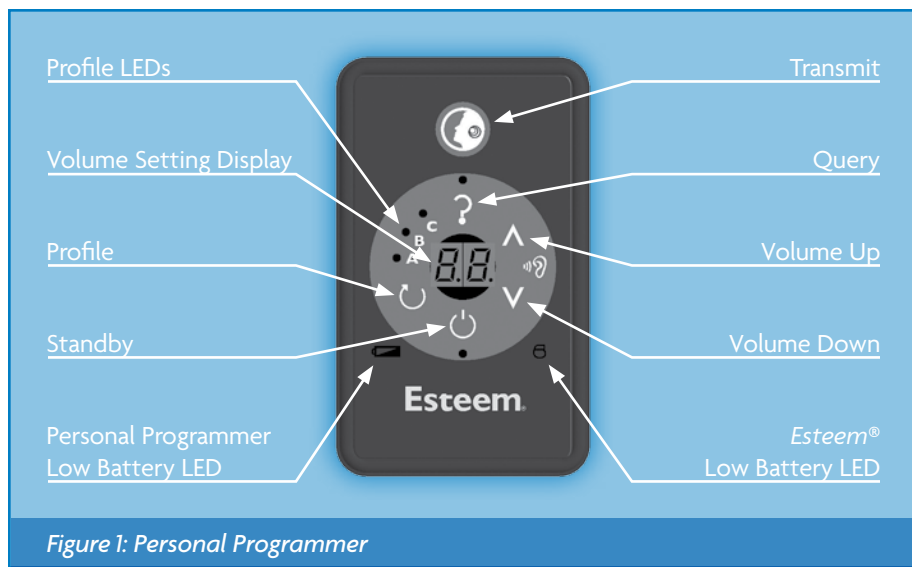


Figure 1: Personal Programmer



*Figure 2: Personal Programmer Placement*

### How to Put Your *Esteem*® in the Standby Mode

The standby mode turns the *Esteem*® “OFF.” The standby mode can help to preserve the battery life of your *Esteem*®. To put the *Esteem*® into standby mode:

1. Turn on the Personal Programmer by pressing and holding the “Standby” button for a few moments; lights will illuminate.
2. Press the “Standby” button (see *Figure 1*), the green LED will illuminate.
3. Locate the “Transmit” button (see *Figure 1*).
4. Hold the Personal Programmer directly over the implanted *Esteem*® (see *Figure 2*).
5. Press the “Transmit” button.
6. Check the LED under the “Standby” button. If the LED under the “Standby” button is steady, the *Esteem*® is in standby. If the LED is blinking, communication was not successful, repeat steps 2-6. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.

## How to Put Your *Esteem*® in the Active Mode and Selecting a Profile

1. Turn on the Personal Programmer by pressing and holding the “Standby” button for a few moments; lights will illuminate.
2. Select the desired profile by pressing the “Profile” button (see *Figure 1*).
3. Locate the “Transmit” button (see *Figure 1*).
4. Hold the Personal Programmer directly over the implanted *Esteem*® (see *Figure 2*).
5. Press the “Transmit” button.
6. Listen for the confirmation tone, and check profile LED on the Personal Programmer. If the LED next to the selected profile is steady, the *Esteem*® is currently in Active Mode in the selected Profile. If the LED is blinking, communication was not successful, repeat steps 2-6. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.

## How to Query Your Current *Esteem*® Settings

1. Turn on the Personal Programmer by pressing and holding the “Standby” button for a few moments; lights will illuminate.
2. Press the “Query” button (see *Figure 1*).
3. Locate the “Transmit” button (see *Figure 1*).
4. Hold the Personal Programmer directly over the implanted *Esteem*® (see *Figure 2*).
5. Press the “Transmit” button.
6. Check Profile LED and Volume Setting Display on the Personal Programmer. If the Profile LED and Volume Setting are steady, the *Esteem*® Query was successful.  
  
If the Query LED is blinking, communication was not successful, repeat steps 2-5. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.

## How To Make Sounds Louder or Quieter

1. Turn on Personal Programmer by pressing and holding the “Standby” button for a few moments; lights will illuminate.
2. Locate the “Volume Up” or “Volume Down” arrows on your Personal Programmer (see *Figure 1*). The “Volume Up” arrow increases the “Volume Setting Display” (see *Figure 1*) and makes sounds louder, and the “Volume Down” arrow decrease the “Volume Setting Display” and makes sounds quieter.
3. Press the “Volume Up” or “Volume Down” arrows to increment the “Volume Setting Display” to the desired volume setting.
4. Locate the “Transmit” button (see *Figure 1*).
5. Hold the Personal Programmer directly over the implanted *Esteem*® (see *Figure 2*).
6. Press the “Transmit” button.

7. Listen for the confirmation tone, and check the “Volume Setting Display” on the Personal Programmer. If the “Volume Setting Display” is steady, the *Esteem*® is currently in Active Mode with the selected Volume setting. If the LED is blinking, communication was not successful, repeat steps 2-7. If communication is still unsuccessful, see the *Personal Programmer Troubleshooting* section.

## How To Turn Off Your Personal Programmer

1. The Personal Programmer has a built-in time-out and after 15 seconds will turn itself off.
2. To manually turn the Personal Programmer off, press and hold the “Standby” button for three seconds. After one second, the volume display will count down from 2 to 0. When the display reaches 0, it will go into “Standby”.

# Use and Care of Your Personal Programmer

Handle the Personal Programmer like other electronic equipment in your home.

Don't put the Personal Programmer near hot appliances such as stoves or irons.

Do not submerge the Personal Programmer in water or liquid. Water or liquids should not enter the Personal Programmer, this will result in a malfunction of the Personal Programmer and potentially void the Personal Programmer warranty.

If the Personal Programmer gets wet due to spill, immediately remove batteries and let sit to dry completely. After an appropriate drying period insert the AAA batteries, if the Personal Programmer malfunctions, contact Envoy Medical Customer Service for replacement.

## Cleaning the Personal Programmer

To clean the Personal Programmer, use a soft water-only dampened cloth to wipe the outside of the Programmer.

## Preventive Inspection and Maintenance

Inspect the Personal Programmer before each use. Do not use a Personal Programmer that shows signs of obvious damage. The Personal Programmer does not require preventive maintenance other than battery replacement upon receiving a low battery indication.

## Personal Programmer Batteries

The Personal Programmer uses two AAA alkaline batteries. When the batteries are good, the Personal Programmer shows a green light when you activate a button to change a setting. Replace the batteries if the indicator shows a yellow light.

## Personal Programmer Battery Replacement

Insert the new batteries properly (positive-positive, negative-negative). Remove the backside battery compartment cover by sliding it off. Remove existing batteries and discard. Orient the new AAA alkaline batteries as shown on the inside of the

battery compartment. Place one end of the battery in first as shown in this picture, then push the other end down into the battery compartment. Slide the cover back into position until it locks into place.



The Personal Programmer is powered by two AAA alkaline batteries. Do not dispose of the batteries along with household waste. Contact your local city office, your household waste disposal service, or where you purchased the batteries for the address of the nearest battery deposit center.

*NOTE: If the Personal Programmer will not be in use for an extended period, remove the alkaline batteries from the Personal Programmer to prevent damage to the device due to battery leakage.*

### Lost or Damaged Personal Programmer

If you lose or damage your *Esteem*® Personal Programmer, please contact Envoy Medical Customer Service for warranty information and replacements.

### *Esteem*® Battery Longevity

The battery life is estimated to be about 4.5 years if the *Esteem*® is left active at all times — that is, if the patient never turns on the Standby Mode. The battery life is estimated to 6.5 years if the *Esteem*® is left active for two thirds of the time— that is, if the Standby Mode is enabled by the patient one-third of the time, or eight hours a day (usually during sleep). The battery life is estimated to nine years if the *Esteem*® is left active eight hours every day.

- **4.5 years** – 24 hours/day, 7 days/week
- **6.5 years** – 16 hours/day, 7 days/week
- **9 years** – 8 hours/day, 7 days/week

*NOTE:* If an *Esteem*® patient is continuously exposed to excessively loud sound levels (90 dB, 24 hours per day) and is using the highest gain settings, battery life can be reduced. Testing under these worst case scenario conditions demonstrated that battery life could be as short as 2.8 years.

### *Esteem*® Battery Elective Replacement Indication (ERI)

The *Esteem*® monitors battery voltage and triggers an ERI when the battery begins to deplete.

The ERI is indicated by a change in the Personal Programmer confirmation tone from a single tone to a dual tone. Also, the “*Esteem*® Low Battery LED” will illuminate on your Personal Programmer.

### *Esteem*® Battery End of Life (EOL)

EOL occurs approximately two weeks after the ERI is first indicated. This assumes that you use the Personal Programmer during this time frame, and can therefore notice the first time that ERI is indicated.

Contact your health care professional immediately when a two-tone confirmation is heard instead of the normal one tone confirmation or when the Personal Programmer shows an illuminated “*Esteem*® Low Battery LED”. This will enable sufficient time to schedule replacement of the *Esteem*® Sound Processor/Battery.

# Personal Programmer Specifications

Power:	2 AAA 1.5V alkaline batteries
Current rating:	463 mA during transmission
Operating Temperature:	15°C to 40°C (59°F to 106°F)
Storage Temperature:	0°C to 50°C (32°F to 122°F)
Leakage Current:	meets the requirements of EN/IEC 60601-1

## Guidance and Manufacturers Declaration - Electromagnetic Emissions

The Model 8001 *Esteem*® Personal Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the *Esteem*® Personal Programmer should assure that it is used in such an environment.

Table 01	Emissions Test	Compliance	Electromagnetic Environment – Guidance
	RF emissions CISPR 11	Group 1	The Personal Programmer must emit electromagnetic energy in order to perform its intended function. Nearby electronics equipment may be affected.
	RF emissions CISPR 11 EN55011	Class A	
	Harmonic emissions EN61000-3-3	Class A	
	Voltage Fluctuations/ flicker emissions EN61000-3-3	Complies	
	EN 300 330	Complies	
	En 60601-1-2 EN 301-489	Complies	



## Guidance and Manufacturers Declaration – Electromagnetic Immunity

The Model 8001 *Esteem*® Personal Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the *Esteem*® Personal Programmer should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV Air ±8kV Contact	±8kV Air ±6kV Contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	NA	Main power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV - Differential mode ±2kV - Common mode	NA	Main power quality should be that of typical commercial or hospital environment.
Voltage dips, short, interruptions and voltage variations on power supply input lines	<5% UT (>95% dip in UT) For 0.5 cycle 40% UT (60% dip in UT) For 5 cycles 70% UT (30% dip in UT) For 25 cycles <5% UT (>95% dip in UT) For 5 sec.	NA	Main power quality should be that of typical commercial or hospital environment. If the user of the Intraoperative System Analyzer requires continued operation during power main interruption, it is recommended that the Intraoperative Analyzer System be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial hospital environment


Table 02

Note: UT is the a.c. main voltage prior to application of the test level.

Guidance and Manufacturers Declaration – Electromagnetic Immunity

The Model 8001 Esteem® Personal Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem® Personal Programmer should assure that it is used in such an environment.

Table 03

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	NA	Portable and mobile RF communications equipment should be used no closer to any part of the Model 8001 Esteem® Personal Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**.  Interference may occur in the vicinity of equipment marked with the following symbol: 			

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

\* Field strengths from fixed transmitters, such as base stations for radio cellular/cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 8001 Esteem® Personal Programmer is used exceeds the applicable RF compliance level above, the Model 8001 Esteem® Personal Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 8001 Esteem® Personal Programmer.

\*\* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Model 8001 Esteem® Personal Programmer

The Model 8001 Esteem® Personal Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 8001 Esteem® Personal Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 8001 Esteem® Personal Programmer as recommended below, according to the maximum output power of the communications equipment.






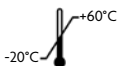





Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			Table 04
	150 kHz to 80 MHz $d=\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$	
.01	NA	0.12	0.23	
.1	NA	0.37	0.74	
1	NA	1.2	2.3	
10	NA	3.7	2.3	
100	NA	11.7	7.4	

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Symbols

Symbol	Description
	Product Serial Number
	Product Model Number
	Protect against dripping water.
	Do not throw in trash.
	Attention, see instructions for use.
	Store at temperatures between -20°C and +60°C.
	Telemetry
	Prescription Only
	Do not use if packaging has been damaged.
	Authorized representative in European Community.
	European Community Mark of Conformity Authorized to affix the CE Mark in 2009.

*CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.*

# Troubleshooting

## Personal Programmer does not turn on:

Batteries may be depleted. Change batteries.

Batteries may be incorrectly inserted. Check battery insertion.

## Personal Programmer communication unsuccessful:

Personal Programmer may be too far away. Reposition Personal Programmer directly over *Esteem*® (see *Figure 2*), paying close attention to distance.

Personal Programmer may be misaligned. Reposition Personal Programmer over *Esteem*® (see *Figure 2*).

**If all troubleshooting attempts fail, please contact Envoy Medical Customer Service for help or replacement.**





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CAUTION: Investigational device. Limited by United States law to investigational use.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

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